UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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| DEBORAH L. MAYLE, *et al.*, | ) | CASE NO. 5: 09 CV 1991 |
| | ) | |
| Plaintiffs, | ) | JUDGE JOHN R. ADAMS |
| | ) | |
| vs. | ) | |
| | ) | |
| STRYKER CORPORATION, *et al.*, | ) | **MEMORANDUM OF OPINION AND ORDER** |
| | ) | |
| | ) | [Resolving Doc. 24] |
| Defendants. | ) | |

This matter is before the Court on the Motion of Defendants Stryker Corporation and Stryker Sales Corporation for Partial Dismissal of Claim for Punitive Damages. (Doc. 24.) The motion is now fully briefed and ready for decision. For the reasons stated below, the motion is DENIED.

**I. Background**

The operative complaint in this matter is Plaintiffs' Second Amended Complaint ("Complaint"), filed on January 12, 2010, against Stryker Corporation and Stryker Sales Corporation (collectively, "Stryker"), Abbott Laboratories ("Abbott") and Hospira, Inc. ("Hospira"). Plaintiffs are Deborah L. Mayle ("Mayle") and her husband, Willard D. Mayle, residents of Stark County, Ohio.

The Complaint alleges that Mayle underwent shoulder surgery in North Canton, Ohio on or about October 30, 2003. Following this surgery, Mayle's doctor affixed subacromially to Mayle's shoulder a pain pump manufactured by Stryker with a continuously injected anesthetic drug, Marcaine. (Complt., ¶ 17.)

Almost three years later, on June 13, 2006, Mayle underwent a second surgery. During the June 13, 2006 surgery, Mayle's shoulder was inspected and revealed "the articular surfaces of the glenoid and humerous to be normal." (*Id.*, ¶ 18.) As with the October 30, 2003 surgery, Mayle's doctor affixed a pain pump to Mayle's shoulder following the June 2006 surgery. This pain pump was placed "intra-articularly, and the pump injected the anesthetic directly into Ms. Mayle's shoulder joint on a continuous basis through a catheter emanating from the pump implanted through the skin into her joint." (*Id.*, ¶ 19.) The pain pump was a Stryker pain pump, reference number 500-120, lot number 2005110701. (*Id.*, ¶ 20.) Abbott and Hospira manufactured the anesthetic drug used in the pump. (*Id.*, ¶ 21.)

Plaintiffs allege that the use of the pain pump in Mayle's second surgery, involving a "continuous injection of anesthetic drugs over time directly into [Mayle's] shoulder joint," caused serious and permanent cartilage damage. (*Id.*, ¶ 22.) Specifically, Mayle "suffered a narrowing of the joint space and/or a condition called 'glenohumeral chondrolysis,' which is the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition." (*Id.*)

Five causes of action are alleged in the Complaint. Count I alleges a statutory products liability claim against Stryker under the Ohio Products Liability Act, Ohio Rev. Code §§ 2307.71 to 2307.80 (the "OPLA"). Count II alleges a claim for punitive damages against Stryker under the OPLA. Count III alleges a statutory products liability claim under the OPLA against Abbott and Hospira. Count IV alleges a claim for punitive damages against Abbott and Hospira.

Count V alleges a claim for loss of consortium against all defendants.[1]

Stryker moves for dismissal of the punitive damage claim alleged against it (*i.e.*, Count II) pursuant to Fed. R. Civ. P. 12(b)(6).

**II. Standard of Review**

In ruling on a motion to dismiss under Fed. R. Civ. P 12(b)(6), the Court construes the complaint and draws all reasonable inferences in the plaintiff's favor and accepts the allegations as true. *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009). "[I]n order to survive a Rule 12(b)(6) motion, the [plaintiff] must provide 'more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will no do.'"; rather, the plaintiff's "'[f]actual allegations must be enough to raise a right to relief above a speculative level.'" *Gunasekera*, 551 F.3d at 466 (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 550 (2007)).

A plaintiff's pleading obligation "does not require heightened fact pleading of specifics, but only enough facts to state a claim for relief that is plausible on its face." *Bassett v. National Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009). And although the Court must accept all well-pleaded factual allegations as true, the Court need not "accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

[1]On January 26, 2010, Plaintiffs filed a stipulation of dismissal without prejudice as to Abbott and Hospira; therefore, the claims against those parties no longer remain in the case.

**III. Analysis**

Stryker contends Plaintiffs' punitive damage claim is precluded by the OPLA. Stryker asserts that Ohio Rev. Code § 2307.80(C) precludes punitive damage claims for medical devices manufactured in accordance with approval from the federal food and drug administration ("FDA") unless the claimant can establish by a preponderance of the evidence that the manufacturer fraudulently and in violation of FDA regulations withheld material information or misrepresented information to the FDA. Specifically, Ohio Rev. Code § 2307.80(C) provides:

> (C)(1) Except as provided in division (C)(2) of this section, if a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product if the drug or device that allegedly caused the harm satisfies either of the following:
>
> (a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C. 201-300cc-15, as amended.
>
> (b) It was an over-the-counter drug marketed pursuant to federal regulations . . . .
>
> (2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type.

Ohio Rev. Code § 2307.80(C).

Stryker contends the pain pump at issue received approval, or "clearance," from the FDA, relying on documents attached as exhibits to its motion. (*See* Exhibits A-E to Stryker's Brief.) Stryker asserts these documents show that the pain pump product alleged to be defective in this case was first cleared by the FDA "via the 501(k) clearance process by Prime Medical

Products, Inc." and that subsequent approvals for revisions to this product were provided to McKinley Medical, LLC and then to Stryker. Stryker contends that, "due to the FDA clearance of the device, the OPLA precludes liability for punitive damages" under Ohio Rev. Code § 2307.80(C)(1)(a). (Stryker Mem. at 11.)

Stryker further contends that Plaintiffs have failed to allege fraud on the FDA with sufficient particularity to trigger the exception set out in Ohio Rev. Code § 2307.80(C)(2). Finally, Stryker contends such state-law claims of "fraud on the FDA" are preempted in any event by federal law, the Medical Devices Amendments of 1976.

Plaintiffs make a number of arguments in opposition to Stryker's motion, including that the documents attached to Stryker's motion may not be considered on a motion to dismiss. Further, Plaintiffs dispute that the documents establish that the pain pump at issue was "manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA]." *See* Ohio Rev. Code § 2307.80(C)(1)(a). Rather, Plaintiffs contend, the pumps were approved only "for use in the intraoperative site" not "in the joint space and not for orthopedic surgeries." (Pltfs. Br. at 2.) The Complaint alleges that use of the pain pumps, as here, "with continuously injected anesthetic in the shoulder joint space" had not been approved by the FDA and, in fact, had been "specifically rejected by the FDA." (Complt., ¶ 28(b).)

The documents attached to Stryker's brief do not provide a sufficient basis for the Court to determine, at this stage of the proceeding, that the pain pump used in Mayle's June 2006 surgery was "manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA]" such that a punitive damage claim is

precluded under Ohio Rev. Code § 2307.80(C)(1)(a). Stryker urges the Court simply to take judicial notice that these documents establish such approval. However, the documents on their face do not make clear that the pain pump at issue in this litigation received FDA approval, and Plaintiffs allege that using pumps as they were here was *rejected* by the FDA. The pleadings must be viewed in the light most favorable to Plaintiff at this stage. Furthermore, the Court will not consider evidence outside of the pleadings in determining this motion to dismiss.

In that the issue of FDA approval of the pain pumps cannot be determined at this stage, dismissal of Plaintiffs' punitive damage claim is not warranted pursuant to Fed. R. Civ. P. 12(b)(6).[2]

**V. Conclusion**

For the reasons stated above, Strykers' Motion for Partial Dismissal of Claim for Punitive Damages (Doc. 24) is denied.

IT IS SO ORDERED.

Dated: March 23, 2010

*/s/ John R. Adams*
JOHN R. ADAMS
United States District Judge

[2]Given that it cannot be determined at this stage whether Ohio Rev. Code § 2307.80(C)(1)(a) applies, it is premature to address Stryker's other arguments, that Plaintiffs failed to plead fraud with sufficient particularity under Ohio Rev. Code § 2307.80(C)(2) and that state law "fraud on the FDA" claims are preempted by federal law.